NOVARTIS | Reimagining Medicine

Third Party Code

Version 2.0

November 2020

Ethics, Risk & Compliance
Policies & Guidelines

Contents

Introduction

While the Novartis purpose - to reimagine medicine to improve and extend people's lives - drives our values and defines our culture of inspired, curious and unbossed, our ethical principles guide us in our everyday decision-making and ensure we act with integrity and do what's right.

Novartis promotes the societal and environmental values of the United Nations Global Compact and United Nations Guiding Principles on Business and Human Rights to its Third Parties and uses its influence where possible to encourage their adoption. The Novartis Third Party Code (the "Third Party Code") is based on the United Nations Global Compact, the United Nations Guiding Principles on Business and Human Rights, and other international standards or accepted good practices. The Third Party Code is aligned with the Novartis Code of Ethics which is binding for all Novartis associates.

Novartis requires its Third Parties to comply with the standards defined in the Third Party Code. Furthermore, our Third Parties are expected to adopt standards that cover the same principles and content included in our Third Party Code with their own suppliers.

Novartis is committed to being a leader in corporate responsibility. This commitment is embodied in the Third Party Code. The Novartis Third Party Risk Management (TPRM) program has been created to extend the Novartis commitment to corporate responsibility to Third Parties. Furthermore, Novartis aims to be a leader and a catalyst for positive change in environmental sustainability. Third Parties are expected to perform beyond legal compliance and actively minimize the environmental impact of their activities and products over their lifecycle.

Novartis is a member of the Pharmaceutical Supply Chain Initiative (PSCI). The Third Party Code is consistent with the Pharmaceutical Industry Principles for Responsible Supply Chain Management for ethics, human rights, labor rights, health and safety, environment and related management systems.

Novartis believes that society and business are best served by responsible business behaviors and practices. Fundamental to this belief is that business should not only operate in compliance with applicable laws, rules and regulations, but that our behaviors address underlying societal concerns. Novartis is aware that differences in local operating environments and laws create challenges in applying our standards as defined in the Third Party Code globally. Novartis also believes that our standards are best implemented through a continual improvement approach that advances Third Party performance over time.

The Third Party Code does not replace local law or labor agreements. Novartis expects Third Parties to operate in compliance with applicable laws, rules, regulations and collective bargaining agreements, in addition to the standards contained herein. Where compliance with the Third Party Code would violate local law or collective bargaining agreements, Third Parties are expected to comply with local requirements while seeking to uphold the principle underpinning the relevant Third Party Code standard.

Robert Weltevreden.
Head of Novartis Business Services

Klaus Moosmayer
Chief Ethics, Risk & Compliance Officer

Links referenced on this page and a glossary of terms used can be found at the end of this document.

Monitoring against our standards

Adherence to the standards contained in this Third Party Code is one of the criteria used in the Novartis Third Party selection and evaluation process.

Novartis expects Third Parties to adhere to applicable legal standards and any higher standards contained herein. Under some circumstances, where the Third Parties have shown and continue to show a material commitment to improvement, Novartis is willing to work with them to bring about improvements through engagement and collaboration. This may include audits, development and progress monitoring of corrective action plans, referring Third Parties to external experts, and other reasonable improvement plans.

Novartis Third Party Standards

1 Human Rights

Novartis is committed to conducting our business in a manner that respects the rights and dignity of all people. We will strive to prevent, mitigate and remedy adverse human rights impacts throughout our workplace, business operations and in the communities in which we work. In order to fulfill this commitment, and in accordance with the United Nations Guiding Principles on Business and Human Rights (UNGPs), Novartis is required to identify, assess and address any human rights risks or impacts in its operations and supply chains. The UNGPs recommend that all companies, regardless of size, sector or operational context, conduct human rights due diligence in order to prevent or mitigate any risks to human rights that they cause, contribute to or are directly linked to their operations, products or services through their business relationships; and to participate in the remediation, in whole or in part, of human rights impacts which they cause or contribute to.

Novartis is committed to working with third parties who operate in a manner that is consistent with our values and ethical principles, including respect for human rights. In addition to the specific requirements regarding labor-related human rights set out under “Section 2. Labor Rights”, third parties are expected and strongly encouraged to conduct human rights due diligence, as set out in the UNGPs, on all internationally recognized human rights, and at a minimum, those expressed in the International Bill of Human Rights (i.e. the Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, and International Covenant on Economic, Social and Cultural Rights) and the principles concerning fundamental rights set out in the International Labour Organization’s Declaration on Fundamental Principles and Rights at Work.

If you have questions about how to conduct human rights due diligence or whether the due diligence you are conducting meets Novartis standards, please contact:
humanrights@novartis.com for guidance and inquiries.

2 Labor Rights – Fair Employment Practices

Third Parties shall be committed to uphold human rights for workers, as set out in the Universal Declaration of Human Rights, and to treat them with dignity, respect and equal opportunity. The labor elements include:

2.1 Freely Chosen Employment

STANDARD

Third Parties shall not use forced labor, including bonded, indentured or involuntary prison labor, or engage in any form of forced labor or human trafficking.

REQUIREMENTS

Forced Labor - Management Systems: A nominated manager with responsibility for Human Resources at each site follows policies and procedures to ensure that all onsite workers have freely chosen to be there and are fully paid for the work they do.

Prison Labor: The use of any prison labor is voluntary and clearly communicated to Novartis, and where used, all applicable local laws or international guidance is followed.

Notice Periods: Workers are free to leave their jobs after reasonable notice and are paid on time and in full for the work they have done prior to leaving.

Retention of Identity Papers/Passports: Workers are not required to hand over original versions of their identity papers or academic certificates to secure employment, unless required to do so by local law. If this is the case, workers have access to their papers at all times.

Freedom of Movement: Workers are able to freely come and go from the site or onsite/offsite accommodation at all times and are not controlled by security guards (e.g. monitored during breaks, followed to the toilets, etc.).

Recruitment Fees and Cash deposits: Workers do not pay recruitment fees, deposits, etc. to secure a job or employer-provided accommodation, nor do they pay excessive “deposits” for tools, training or personal protective equipment necessary to carry out their jobs safely.

2.2 Child Labor and Young Workers

STANDARD

Third Parties shall not use child labor. The employment of young workers below the age of 18 shall only occur in non-hazardous work and when young workers are above a country’s legal age for employment and the age established for completing compulsory education.

REQUIREMENTS

Child Labor - Management Systems: A nominated manager with responsibility for Human Resources ensures that there are adequate policies and procedures in place to monitor the ages of workers at each site.

Child Labor: Children below the local minimum working age, the age of compulsory education or the ages set out in the International Labor Organization Core Conventions (whichever is higher) are not employed subject to the exception for Light Work (see Glossary of Terms).

A child is:

- Any young person below 15 years of age (or 14 years of age in countries whose economy and educational facilities are insufficiently developed), in accordance with Article 2 of ILO Convention 138 (Minimum Age Convention, 1973).
- Any young person below the local legal minimum working age where this is higher than 15 years of age (or 14 years of age, as the case may be).
- Any young person below the age of local legal compulsory education where this is higher than 15 years of age (or 14 years of age, as the case may be).

Remediation: If children are found engaged in prohibited child labor, an immediate and appropriate remediation procedure is put in place, to ensure the welfare of the child, taking into account the best interests of the child. If children are found working, Third Parties shall:

- Remove the child from the workplace immediately, unless this is not in the best interest of the child

- Put in place a suitable plan to support the child, which may involve covering the cost of formal or vocational training, accommodation or other costs as necessary.

Young Workers: Young people under the age of 18, legally able to work, do not carry out any hazardous work (chemical handling, strenuous physical labor, etc.) or night shifts, and all applicable local laws are followed, including access to education, training, health checks and number of hours allowed to work, etc.

2.3 Non-Discrimination

STANDARD

Third Parties shall provide a workplace free of discrimination. Discrimination for reasons such as race, national or ethnic minority status, ethnicity, color, age, sex, sexual orientation, gender, gender identity or expression, social origin, disability, religion, political affiliation, union membership, pregnancy, marital status or any other protected category as defined by local laws is not tolerated.

REQUIREMENTS

Non-Discrimination - Management Systems: A nominated manager with responsibility for Human Resources ensures adequate policies and procedures are in place at each facility to prevent discrimination as well as manage effective disciplinary procedures. All workers know to whom they can report incidences of discrimination.

Non-Discrimination: Workers do not face discrimination at any time (from recruitment to leaving employment) for any reason such as race, national or ethnic minority status, ethnicity, color, age, sex, sexual orientation, gender, gender identity or expression, social origin, disability, religion, political affiliation, union membership, pregnancy, marital status or any other protected category as defined by local laws. Potential recruits are not pregnancy-tested unless required by local law and pregnant women are not discriminated against in accordance with local laws.

2.4 Fair Treatment

STANDARD

Third Parties shall provide a workplace free of and with no threat of harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of workers.

REQUIREMENTS

Fair Treatment - Management Systems: A nominated manager with responsibility for Human Resources ensures adequate policies and procedures are in place so that all workers receive fair treatment. Workers understand disciplinary and grievance procedures, and fines imposed on workers as part of a disciplinary action are legal and fair.

Supervisors, managers or co-workers found abusing workers are disciplined accordingly.

Harassment or Abuse: Workers neither face nor are threatened with bullying, sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse.

Role of Security Personnel: Workers are not subject to unreasonable body searches. Physical security searches are only carried out by authorized bodies, according to local legal standards, and by same-sex security guards.

Fair Treatment - Bribery: Workers do not have to pay other workers to avoid victimization or preferential treatment.

2.5 Wages, Benefits and Working Hours

STANDARD

Third Parties shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits.

Third Parties shall communicate in a timely manner with workers regarding the basis upon which they will be paid. Third Parties are also expected to communicate with the worker whether overtime is required and the wages to be paid for such overtime.

REQUIREMENTS

Wages and Working Hours - Management Systems: A system is in place to monitor the hours and wages paid to all agency staff on the Third Party site, and complete hours and payroll records are kept for all workers on the Third Party site at all times.

Wages: Workers are not required to do unpaid work. Workers' monthly pay, or piece rate, is at least at local legal minimum wages or industry benchmarks, if higher than local standards, and is paid regularly and in full, in accordance with local laws.

Overtime - Pay: Overtime shall be compensated at a premium rate, in accordance with national law or collective agreements, whichever is legally applicable. Where these do not exist, overtime pay shall be no less than 1.25 times regular pay.

Benefits and Bonuses: All legally required benefits and bonuses are paid to workers on time and in full.

Standard Working Hours: Standard working hours shall not exceed eight hours per day or 48 hours per week (or 56 hours per week on average for shiftwork processes).

Overtime Hours: Overtime hours shall not exceed the limits established in national law or under collective agreements, whichever is legally applicable. Where these do not exist, overtime hours shall be limited to the degree necessary to ensure the health and safety of workers. Mandatory overtime within these limits does not constitute forced labor. Overtime outside these limits that is made compulsory by threats of a penalty, except in the case of emergencies, constitutes forced labor, irrespective of the reasons for such overtime.

Time-off and Breaks: Workers are given time off and breaks in accordance with local laws. The Third Party should strive to meet ILO standards where these are higher.

Leave: Paid sick leave is to be provided separate from vacation days or other holidays, and does not count against vacation or holiday time off. Paid public holidays shall be in accordance with local law. Paid vacation days shall be given in accordance with local law, and the Third Party should strive to meet ILO standards, where these are higher. Paid parental leave (including for mothers, fathers, adoptive parents, or other parents as defined by local law) shall be given in accordance with local law. The Third Party should strive to meet ILO standards or industry benchmarks, where these are higher than local law.

Communication: Payment terms are communicated to workers before they start and are confirmed in writing. Workers receive written pay slips. All workers must have a written contract in a language they understand (this requirement includes all terms of employment and not only wages and benefits).

Deductions: Deductions for disciplinary issues, lateness and absence are only taken in accordance with local laws.

2.6 Freedom of Association and Collective Bargaining

STANDARD

Open communication and direct engagement with workers to resolve workplace and compensation issues are encouraged.

Third Parties shall respect the rights of workers, as set forth in local laws, to freely form or not form, to join or not join, labor unions, seek representation and join workers' councils. Workers shall be

able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.

REQUIREMENTS

Collective Bargaining: Workers are able to bargain collectively and understand how to raise issues if they wish. Where collective agreements are in place, they are communicated to all workers in a language they can understand.

Trade Union/Worker Representation Rights: Workers are freely able to form or not form, to join or not join, a trade union or worker committee without fear of reprisal or discrimination. Worker representatives are granted reasonable time and access to facilities, such as meeting rooms, to carry out their role, in accordance with local laws.

Parallel Means: Where local laws restrict trade unions, workers are able to form worker committees, if they so choose.

Health and Safety and Environmental Sustainability

Given the breadth, complexity and size of the Novartis supply chain, the standards outlined in sections 3 and 4 for Health, Safety and Environmental Sustainability (HSE) provide Third Parties with basic standards and concepts that Novartis expects adherence to throughout its supply chain.

Novartis expects each Third Party to understand the applicable HSE standards for its specific products or services and to augment these standards with the additional product/service-specific standards as necessary. The effectiveness of the protection needs to be verified by trained and experienced or certified subject matter experts.

3 Health and Safety

Third Parties shall comply with all applicable health and safety laws and regulations by providing a safe and healthy working environment and, if applicable, safe and healthy company living quarters. The health and safety elements include:

3.1 Hazard Information

STANDARD

Third Parties shall have programs and systems in place to provide workers with safety information relating to hazardous materials and education to protect them from potential hazards. Hazardous materials can include but are not limited to raw materials, isolated intermediates, products, solvents, cleaning agents and wastes.

3.2 Risks and Process Safety

STANDARD

Third Parties shall have systems and programs in place to identify both occupational and process hazards as well as potential impacts on surrounding communities. They should quantify such hazards, define the risk levels appropriately and have programs and systems in place to prevent or mitigate these risks (e.g. catastrophic releases of chemicals, fumes, dust).

3.3 Worker Protection

STANDARD

Third Parties shall have systems and processes in place to protect workers from exposure to chemical, biological and physical hazards (including physically demanding tasks) in the workplace and company-provided living quarters.

3.4 Emergency Preparedness and Response

STANDARD Third parties shall develop and distribute emergency plans across their facilities and company-provided living quarters and surrounding communities. Third Parties should minimize the potential impact of any emergency by implementing suitable emergency plans and response procedures.

4 Environmental Sustainability

Third Parties shall comply with all applicable environmental laws and regulations. They are expected to act beyond legal compliance and actively minimize the environmental impact of their activities and products over their lifecycle, specifically:

4.1 Environmental Targets and Sustainability Performance

STANDARD Our ambition is to be a catalyst for change and the leader in environmental sustainability. We shall drive sustainability through our own operations and ultimately across our value chain to become carbon neutral, plastic neutral and water sustainable, before the end of 2030. It is expected that Third Parties actively contribute and support us to achieve our ambitious environmental targets through collaboration with us and implementation of environmental improvement opportunities.

STANDARD We expect our Third Parties to set sustainability goals and targets linked to issues material to their industry, and we encourage those that make a commitment to improve and invest in these areas as well as being transparent about their environmental practices and performance. It is expected that Third Parties demonstrate progress towards those targets and participate in assessments that baseline and monitor their sustainability performance.

STANDARD We expect our Third Parties to engage with their suppliers to actively minimize the environmental impact of their supply chain.

4.2 Environmental Authorizations

STANDARD Third Parties shall have processes and systems to conform with applicable environmental laws and regulations. Required environmental permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

4.3 Waste and Emissions

STANDARD Third Parties shall have processes and systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste. Any generation and disposal of waste, emissions to air and discharges to water, with the potential to adversely impact human health or the livelihoods or way of life of surrounding communities or the environment (giving priority to Active Pharmaceutical Ingredients) shall be appropriately minimized, properly managed, controlled and/or treated prior to release into the environment.

STANDARD Third Parties who manufacture or formulate Active Pharmaceutical Ingredients (APIs) have to demonstrate safe discharge levels for releases to the aquatic environment and conform to the AMR Industry Alliance Manufacturing Framework (further details and information under https://www.amrindustryalliance.org/)

.

4.4 Spills and Releases

STANDARD Third Parties shall have processes and systems in place to prevent and mitigate accidental and diffusive spills and releases to the environment. They shall remedy any impacts that are caused.

4.5 Sustainability and Efficiency of Resources

STANDARD Third Parties shall have processes and systems in place to strive for a positive effect on climate, by reducing their carbon footprint, waste and water usage and making efficient use of natural resources. As members of society, we have to protect the environment for future generations.

Where surrounding communities rely on ecosystem services for their sustenance or livelihoods, Third Parties shall ensure that their use of natural resources does not adversely impact community members' rights to water and an adequate standard of living and they shall remedy any impacts that are caused.

5 Animal Welfare

STANDARD

Animals shall be treated respectfully, with pain and stress minimized. Animal testing should be performed after consideration to replace animals, reduce the numbers of animals used or refine procedures to minimize distress. Alternatives should be used wherever scientifically valid and acceptable to regulators.

REQUIREMENTS

Novartis is committed to globally achieving high standards of Animal Welfare whenever animals are involved in a Novartis study or procedure. The Novartis Animal Welfare Standard applies to all internal and Novartis external animal studies. It corresponds with the US regulations, namely the AW Act (USC 7; 1966) and Regulations, and the US Guides for the Care and Use of Laboratory and Agricultural Animals (including all vertebrates). More stringent criteria apply for Non-Human Primates.

Third Parties are required to comply with all applicable local and national laws and regulations relating to Animal Welfare. In addition, they are required to comply with the following key principles, which embody the Third Party requirements of the Novartis Animal Welfare Policy (where local/national laws and regulations impose stricter requirements, the stricter requirements shall be followed):

- The welfare of animals is of primary concern.
- The 3Rs (Replace, Reduce, Refine) are applied.
- Studies are carried out by well-trained, competent and experienced personnel.
- Finished cosmetics and their ingredients will not be tested on animals.
- Only animals specifically bred for research purposes are purchased and used, except for some farm animals, companion animals used in clinical studies and fish.
- Animals are treated respectfully and cared for in accordance with the particular needs of the given species and individual, as defined by current veterinary care and practice guidelines for animals used in experiments.
- Animals experience the minimum amount of discomfort, distress or pain and appropriate methods for sedation, analgesia or anesthesia are utilized whenever possible.
- Particular care and attention is paid to the transportation of animals, including use of appropriate and adequate devices and/or facilities for transport in accordance with applicable guidelines and legal requirements.
- The principles and requirements apply to Novartis-initiated studies performed at Third Party facilities (e.g. contract research organizations, universities and other companies).

6 Anti-Bribery and Fair Competition

6.1 Anti-Bribery

STANDARD

Third Parties shall not bribe any public official or private person and shall not accept any bribes. No intermediaries, such as agents, advisers, distributors or any other business partners, shall be used to commit acts of bribery.

Third Parties shall comply with applicable laws and regulations and industry standards related to anti-corruption.

REQUIREMENTS

Facilitation Payments: Novartis prohibits any facilitation payments being made in the context of any Novartis business.

Gifts, Hospitality and Entertainment: Gifts, hospitality and entertainment will not be given, offered or promised to be given to receive anything of value for the purpose of improperly influencing any decisions concerning the Third Party and/or Novartis. The Third Party will not use other third parties to commit acts of bribery or corruption. Gifts, hospitality and entertainment are modest, reasonable and infrequent, so far as any individual recipient is concerned. However, no gifts of any kind including personal gifts or promotional aids, etc., whether branded or unbranded, can be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates).

Grants, Donations and Sponsorship: Grants and donations are only given if the Third Party and/or Novartis do not receive, and are not to be perceived to receive, any tangible consideration in return. Grants and donations must never reward, or be perceived to reward, any tangible consideration. Sponsorship is not to be used (or perceived to be used) to receive an improper commercial advantage in return. Sponsorship must never reward (or be perceived to reward) an improper commercial advantage.

Political Contributions: If the Third Party chooses to make political contributions, they must be made in compliance with all applicable laws, regulations and industry codes and standards, and must not be made with the expectation of direct or immediate return for the Third Party or Novartis.

Lobbying: Lobbying is not to be misused for any corrupt or illegal purposes, or to improperly influence any decision.

Public Officials: Any relationship between the Third Party and public officials is in strict compliance with the rules and regulations to which they are subject (i.e. any applicable rules or regulations in the particular country relating to public officials or that have been imposed by their employer). Any benefit conveyed to a public official is fully transparent, properly documented and accounted for.

6.2 Fair Competition

STANDARD

Third Parties shall conduct their business consistent with fair competition. They shall employ fair business practices, including accurate and truthful advertising.

Third Parties shall comply with all fair competition and antitrust laws and regulations.

7 Data Privacy and Information Protection

STANDARD

Third Parties shall establish and maintain adequate personal data and information security protection for the information that they, and any third parties acting on their behalf, process.

Third Parties shall operate in a manner that is consistent with applicable data protection/privacy laws and aligned with industry standards for the protection and security of all information, including Personal Information.

REQUIREMENTS

Proper Protection of Personal Information: Third Parties shall have the proper organizational structure, processes and procedures to ensure the protection, confidentiality, integrity and availability of information against accidental, unauthorized or unlawful loss, destruction, alteration, disclosure, use or access.

Proper Security Measures: Third Parties must have adequate policies and procedures in place, which address technical and organizational security, and take reasonable steps to stay current and to confirm on a periodic basis, compliance with those. Such policies and procedures must include for Suppliers only, at minimum, the Minimum Information Security Controls for Suppliers, available at: (https://www.novartis.com/our-company/corporate-responsibility/reporting-disclosure/codes-policies-guidelines).

Compliance with Cross-Border Transfer Restrictions: Third Parties must have adequate safeguards, rules and procedures to ensure that they remain in compliance with all applicable laws that govern cross-border data transmissions, where applicable.

Data and/or Information Breach Notification: Third Parties shall notify Novartis for any suspected or actual data breach concerning the services/deliverables/goods provided. Third Parties shall appropriately assist Novartis in any investigations in response to a data or information breach.

8 Responsible Minerals

STANDARD

Third Parties shall support Novartis commitment to seek to identify, reduce and, where possible, eliminate the use of certain minerals known as 3TG that have been identified as included in Novartis products and that have been determined to have directly or indirectly financed or benefitted armed groups in the Democratic Republic of Congo (DRC) or its adjoining countries.

REQUIREMENTS

Third Parties shall:

- Help identify the source of 3TGs in products, components or materials supplied to Novartis by Third Parties (including the smelter or refiner where such 3TGs were processed and the country of origin of the 3TGs where possible through reasonable means)
- Cooperate with Novartis in its due diligence process and in responding to its requests for information relating to minerals used in our products
- Provide, upon request, reasonable evidence of the Third Party's performance of similar due diligence with respect to any of their suppliers or sub-contractors involved in the production of the materials or products supplied to Novartis or any components of those materials or products
- Work with Novartis to assess opportunities for alternative sources where 3TG responsible minerals are identified.

9 Quality (Good Manufacturing Practices)

STANDARD

Third Parties shall ensure that they are providing materials, products and services that comply with applicable laws, regulations, health authority standards, industry guidance and any additional customer requirements.

Third Parties shall, where applicable, abide by the Quality Contract in place governing Good Manufacturing Practices (GMP) activity, expectations and requirements.

REQUIREMENTS

Third Parties that are subject to GMP requirements shall:

- Hold and maintain the necessary manufacturing licenses, permits and registrations (or comparable authorizations) in respect of the materials, products and/or services supplied to Novartis and for the relevant facility issued by relevant regulatory authorities
- Ensure that all data relevant for any activities conducted to provide materials, products and/or services to Novartis, is accurate, controlled, safe from manipulation or loss and compliant with all health authority standards and industry expectations for data integrity
- Take measures to ensure security and integrity of the supply chain, including but not limited to measures for anti-tampering, anti-counterfeiting and product serialization requirements, etc.
- Cooperate with Novartis in implementing new or changed health authority standards or expectations in time for regulatory implementation.

10 Trade Sanctions and Exports Control

STANDARD

Third Parties shall identify and comply with applicable trade sanctions and export control laws, including but not limited to US, EU and Swiss trade sanctions laws. Novartis does not engage with persons or companies that have been placed by governments on sanctioned party lists.

REQUIREMENTS

Third Parties shall:

- Confirm that neither they nor their affiliated companies, shareholders or directors have been previously, or are currently, placed on one of the following restricted parties lists: the U.S. List of Specially Designated Nationals ("SDNs") and Blocked Persons, maintained by the U.S. Treasury Department Office of Foreign Assets Control; the Debarred List and non-proliferation sanctions lists maintained by the U.S. State Department; the EU Consolidated List of Designated Parties; and the Sanctions Embargoes List of Switzerland;
- Confirm they are not currently owned 50% or more, individually or in the aggregate, by one or more SDNs;
- Shall immediately inform Novartis by email (using the mail address: nto_trade.sanctions@novartis.com) if during the course of dealings with Novartis: (i) they, their affiliated companies, shareholders or directors are placed on one of the restricted parties lists referenced above; or (ii) they become owned 50% or more, individually or in the aggregate, by one or more SDNs.

11 Identification of Concerns

STANDARD

All workers should be encouraged to report concerns or illegal activities in the workplace, without threat of reprisal, intimidation or harassment. Third Parties shall investigate and take corrective action, if needed.

All workers may also report any concerns about work being done on behalf of Novartis to our SpeakUp office through a web-based platform or by e-mail to: speakup@novartis.com

12 Management Systems

Third Parties shall use management systems to facilitate continual improvement and compliance with these standards. Elements of the management systems include:

12.1 Commitment and Accountability

STANDARD

Third Parties shall demonstrate commitment to the concepts described in this document by allocating appropriate resources.

12.2 Legal and Customer Requirements

STANDARD

Third Parties shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

12.3 Risk Management

STANDARD

Third Parties shall have mechanisms to determine and manage risk in all areas addressed by this document.

12.4 Third Party Relationships

STANDARD

Third Parties do not sub-contract or otherwise engage with third parties on behalf of Novartis or represent Novartis to third parties, without the prior written consent of Novartis. Similarly, there is no assignment of the contract, without prior written consent of Novartis.

12.5 Audit Right

STANDARD

Novartis may audit (or engage a third party to audit on their behalf) the Third Party at any time upon reasonable prior notice, to ensure its compliance with the standards in the Third Party Code, and to confirm all payments made by Novartis and to third parties on behalf of Novartis. Supplemental audit provisions may also apply as agreed between the parties.

12.6 Documentation

STANDARD

Third Parties shall maintain documentation necessary to demonstrate conformance with these standards and compliance with applicable regulations.

REQUIREMENTS

Third Parties shall prepare and maintain books and records that document accurately and in reasonable detail all matters related to business with Novartis, accounting for all payments (including gifts, hospitality and entertainment, or anything else of value) made on behalf of Novartis, or out of funds provided by Novartis.

"Off-the-books" accounts and false or deceptive entries in the Third Party's books and records are prohibited. All financial transactions must be documented, regularly reviewed and properly accounted for. A copy of this accounting is available to Novartis upon request.

Third Parties shall ensure that all relevant internal financial controls and approval procedures are followed and that the retention and archive of books and records is consistent with the Third Party's own standards and tax and other applicable laws and regulations. More specific record retention requirements may be agreed between the parties.

12.7 Training and Competency

STANDARD

Third Parties shall educate their employees to make ethical decisions in compliance with laws, regulations and contract requirements. If requested by the Third Party, Novartis has the right to train.

12.8 Continual Improvement

STANDARD

Third Parties are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, audits, inspections and management reviews.

12.9 Business Continuity Management

STANDARD

Third Parties should consider having Business Continuity measures in place for products and services being provided to Novartis, in the case of a disruptive incident.

Acknowledgement

The Third Party acknowledges that their engagement is not used by Novartis to create an incentive or reward for prescribing Novartis products or to secure any improper business advantage for Novartis.

Disclaimer

Novartis may, in its sole discretion, provide guidance, documents, information, advice, best practice sharing, know-how, insights and/or examples ("**Guidance**") to the Third Party for the purpose of its compliance with this Third Party Code. The Third Party acknowledges and agrees that any such Guidance is provided by Novartis for information purposes only and is not a substitute for professional advice and/or compliance with applicable legal requirements. The Third Party places reliance on Novartis Guidance at its own risk and any consequences of decisions relating to, or the implementation of, such Guidance are the sole responsibility of the Third Party. Novartis does not warrant and makes no representations as to the accuracy or completeness of such Guidance and will not be held responsible by any person, including the Third Party, in any manner whatsoever, for any consequences of the Third Party's reliance on or implementation of such Guidance.

Glossary of Terms

3TG: Tin (Cassiterite), Tantalum (Coltan, Columbite-Tantalite), Tungsten (Wolframite) and Gold as defined in the 2010 Dodd-Frank Act, Section 1502.

Data Protection Laws/Legislation:

a. The General Data Protection Regulation (2016/679)

b. All other existing or new applicable laws/regulations relating to or impacting on the processing of Personal Data of a data subject and/or its privacy.

Donation: Benefit granted by Novartis to legitimate organizations for an altruistic and specified purpose, where Novartis does not expect (and there is no agreement or intention) to receive any benefit, consideration or service in return.

Grant: Independently requested contribution conveyed to a legitimate organization for a specified purpose without expectation, agreement or intent to receive any tangible benefit (a measurable or quantifiable and objective benefit).

GMP (Good Manufacturing Practices): System for ensuring that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.

Healthcare Professional (HCP): Any member, student, or researcher of the medical, dental, optometry, opticianry, pharmacy or nursing profession, or any other persons, social workers, clinical psychologists, formulary committee members and pharmacy & therapeutics (P&T) committee members, who in the course of his or her professional activities provides medical services and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, or use pharmaceutical products and/or medical technologies, and all members of their office staff.

Human Trafficking: The transporting, harboring, recruiting, transferring or receiving of persons by means of threat, force, coercion, abduction or fraud, for labor or services.

Light Work: ILO Conventions include the concept of "light work", i.e. children below 15 years of age can perform non-hazardous light work for a limited number of hours per week as long as it does not interfere with their schooling (i.e. 13-15 year olds in developed countries and 12-14 year olds in less developed countries).

Personal Data/Personal Information:

a. Any information relating to an identified or identifiable person, including without limitation electronic data and paper-based files that contain information such as name, home address, office address, e-mail address, age, gender, family information, profession, education, professional affiliations or salary

b. Non-public personal information, such as national identification number, passport number, social security number, driver's license number

c. Health or medical information, such as insurance information, medical prognosis or treatment, diagnosis information or genetic information; and including coded clinical trial patient data

d. Sensitive personal information, such as race, religion, disability, trade union memberships or sexuality

e. Any data or information that is qualified as Personal Information or Personal Data under the applicable Data Protection Legislation.

Quality Contract: A quality contract is a legal agreement that helps to assign the quality assurance responsibilities between the contract giver and contract acceptor for current GMP requirements and compliance, details any specific requirements regarding the product provided via written specifications, establishes the expectations for providing acceptable services, quality processes, analysis and/or products and ensures the agreed upon quality activities between the parties involved are carried out.

Sponsorship: Agreement by which Novartis, for the mutual benefit of Novartis and the sponsored party, provides funding to establish an association between the Novartis image, brands or services and a sponsored event, activity or organization.

Standards: Collectively, the standards and corresponding requirements set out in this Third Party Code.

Third Party/Third Parties: For the purpose of the scope of the Third Party Code, this means the following third parties:

- **Suppliers:** An external natural or legal person/entity outside the Novartis Group from whom Novartis sources goods or services. This includes, for example:
  i. Contract Manufacturing Organizations (CMOs)
  ii. Institutions and collaborators carrying out research for or on behalf of Novartis, where Novartis is acting as the sponsor and paying for the research, including collaborators of both Contract Research Organizations (CROs) and Academic Research Organizations (AROs)
  iii. Third Parties that handle or distribute Novartis products (i.e. logistics services) where the ownership of the products is not transferred to the Third Party service provider
  iv. HCPs acting as "third parties" only, i.e. where they provide goods or services against a fee for a service beyond their profession as an HCP, such as app developers or commercial/marketing consultants, etc. (otherwise HCPs are out of scope).
- **Business Development & Licensing (BD&L):** Any Third Party with whom a product in-licensing agreement has been contracted with Novartis.
- **Distributors and Wholesalers:** Any Third Party that imports and/or resells for its own business purposes Novartis Products (whether or not they provide promotion services for the specific Novartis Products on behalf of Novartis).

Worker: Any employee, director, officer, staff or personnel engaged or employed by a Third Party, including agency workers, whether on a permanent, temporary or casual basis.

References and Bibliography

The following references are included for information. They are not intended to create any additional obligations beyond this Novartis Third Party Code.

General References	Novartis Code of Ethics Pharmaceutical Supply Chain Initiative United Nations Global Compact Universal Declaration of Human Rights United Nations Guiding Principles on Business and Human Rights
Labor Rights	**Freely Chosen Employment** **International Labor Organization** ("ILO") Conventions 29 and 105: https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12000:0::NO::: **Child Labor** ILO Conventions 138 and 182: https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12000:0::NO::: **Non-Discrimination** ILO Conventions 111 and 100 : https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12000:0::NO::: International Convention on the Elimination of All Forms of Racial Discrimination: https://ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx Convention on the Elimination of All Forms of Discrimination Against Women: https://www.ohchr.org/EN/ProfessionalInterest/Pages/CEDAW.aspx **Violence and Harassment** ILO Convention 190 and Recommendation 206 **Wages, Benefits and Working Hours** ILO Conventions 131, 95, 14 and 1 https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12000:0::NO::: **Freedom of Association** ILO Conventions 87 and 98: https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12000:0::NO:::
Health, Safety & Environment	OHSAS 18001 ISO 14001 Environmental Management Systems standard ISO 50 000 Energy Management Systems standard Forest Stewardship Council Sustainable Palm Oil
Animal Welfare	Guide for the Care and Use of Laboratory Animals, 8th Edition (©2011) National Research Council (NRC), Washington DC, USA Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 3rd Edition (2010), Federation of Animal Science Societies (FASS), Champaign IL, USA European Directive 2010/63/EU (PE-CONS 37/10) of the European Parliament and of the Council of the European Union on the Protection of Animals used for Scientific Purposes (2010)
Anti-Bribery	UN Convention Anti Bribery OECD Anti-Bribery Convention US Foreign Corrupt Practices Act 1977 UK Bribery Act 2010

Novartis International AG, P.O Box CH-4002 Basel, Switzerland
Tel: +41 61 324 11 11 | www.novartis.com

Version 2.0 | Nov 1, 2020